

## 510(K) Summary

### Disc-O-Tech Medical Technologies Ltd. Fixion Interlocking Nailing System

#### Company Name

Disc-O-Tech Medical Technologies, Ltd.  
3 Hasadnaot St. Herzelia  
Israel, 46728

#### Submitter's Name and Contact Person

Jonathan S. Kahan, Esq.  
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Washington, DC 20004  
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#### Date Prepared

June, 2000

#### Trade/Proprietary Name

Fixion<sup>TM</sup> Interlocking Nailing System

#### Classification Name

Intramedullary Fixation Rod  
21 C.F.R. § 888.3020  
Class II

#### Predicate Devices

1. Fixion Intramedullary Nailing System (K990717) by Disc-O-Tech.
2. Seidel Humeral Locking Nail (K883882, K924004, K925544, K931256) by Howmedica.
3. Universal Tibial Nail (K914453) by Synthes.
4. Unreamed Femoral Nail (K923580) by Synthes.
5. Unreamed Humeral Nail (K933518) by Synthes.
6. True/Flex Upper Extremity IM Nail (K902264) by Encore (Applied Osteo Systems, Inc.)

#### Performance Standards

The following standards were used:

1. The Interlocking Nail is manufactured from 316L Stainless Steel, which meets the requirements of ASTM F138 - Standard Specification for Stainless steel Bar and Wire for Surgical Implants.
2. The 4 point bending mechanical testing was performed according to ASTM F1264 - Standard for Mechanical Performance Considerations for Intramedullary Fixation Devices.
3. The torsional mechanical testing was performed according to ASTM F383 - Standard

## Practice for Static Bend and Torsion Testing of Intramedullary Rods.

### Intended Use

The *Fixion Interlocking Nailing System* ("Fixion IL") is intended for use in fixation of fractures in the humerus, femur and tibia. In humerus and tibia fractures it is indicated for use in shaft fractures that are 5cm below the surgical neck to 5cm proximal to the distal end of the medullar canal. The Fixion IL may be used in femur shaft, femur neck, and proximal femur fractures. The Fixion IL is also indicated for use in comminuted shaft fractures and fractures that generate short distal or proximal fragments.

### System Description

The Fixion Interlocking Nailing System is a single use system that consist the following components:

1. The **Nail implant** is an expandable non-slotted stainless steel cylindrical tube, with a cap protected, female threaded proximal end with holes for interlocking screws to lock the nail in the bone. The **Nail implant** may also have both proximal and distal ends with holes for interlocking screws.
2. The **Inflation device** is a single-use manual plastic pump that is filled with sterile inflation liquid.

Once the nail is positioned within the medullary canal, rotation of the "pump" handle allows for nail diameter increase to its intended diameter under X-ray and controlled pressure. After the expansion of the nail, the interlocking screws are used to lock the nail inside the bone.

### Substantial Equivalence

The Fixion Interlocking Nailing System Nail has substantially equivalent intended use and indications for use as the Fixion™ Intramedullary Nail and the other predicates, i.e., fixation of long bone fractures of the humerus, tibia, and femur.

The performance characteristics of the Fixion Interlocking Nail have been tested and found to meet the specifications through a series of bench and animal tests.

The Fixion Interlocking Nail, like the Fixion™ Intramedullary Nail, Seidel Humeral Locking Nail and the Universal Tibial Nail is made of 316L Stainless Steel and has canulated design. The cross section of the Fixion Interlocking and the Fixion Intramedullary nails is circular with reinforcement bars.

Fixation of the Fixion Interlocking and Intramedullary nails is achieved by inflation and results in the attachment of the 4 reinforcement bars to the medullary canal wall. The addition of interlocking screws provides equivalent fixation to the end of the nail, in a manner that is substantially equivalent to that of the Seidel Humeral Locking, Unreamed Humeral, Universal Tibial and Unreamed Femoral nails. The inflation of the Fixion Interlocking nail with saline, which is a non-compressible biocompatible fluid, is identical to the cleared Fixion IMN nail and does not raise any new safety and efficacy issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC - 5 2000

Mr. Johnathan S. Kahan, Esq.  
Disc-O-Tech Medical Technologies, LTD.  
c/o Hogan & Hartson L.L.P.  
Columbia Square  
555 Thirteenth Street, N.W.  
Washington, DC 20004-1109

Re: K002783

Trade Name: Fixion Interlocking Nail (Fixion IL Nail)  
Regulatory Class: II  
Product Code: HSB  
Dated: August 30, 2000  
Received: September 6, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

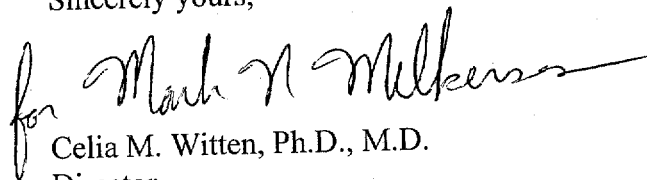
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. Johnathan S. Kahan, Esq.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Milken", is written over the typed name "Celia M. Witten, Ph.D., M.D.". The signature is fluid and cursive.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### Indication for Use

510(K) Number (if known): 002783

Device Name: Fixion Interlocking Nailing System

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(per 21 CFR 801.109)

OR

Over the Counter Use \_\_\_\_\_

for Mark N. Milburn  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number 002783